

## **INTRAUTERINE CONTRACEPTION (IUC)**

### **I. INTRODUCTION**

Intrauterine contraceptive devices (IUCs, also commonly referred to as IUDs) are safe, highly effective, long-term, reversible and cost effective. Worldwide, IUCs are the most commonly used reversible contraceptive method. In the United States, IUC is increasing in popularity. The CDC reports that between 2006 and 2013, IUD use increase by 83%. There are two types of IUCs available: the levonorgestrel-releasing IUCs (LNG-IUD) and the copper-containing IUD (Copper T380A, or TCu380A or Cu-IUD).

- A. There are five FDA approved long-term intrauterine contraceptive methods available in the United States (please refer to comparison table below):
  - 1. Levonorgestrel-releasing IUCs (LNG-IUD) – the mechanism of action is the same, each device has slight variations in doses of levonorgestrel and size
    - a. Mirena® Levonorgestrel-Releasing Intrauterine System approved 2000, 5-year effectiveness, 20.0 mcg/day dose of levonorgestrel
    - b. Skyla® Levonorgestrel-Releasing Intrauterine System approved 2013, 3-year effectiveness, 14.0 mcg/day dose of levonorgestrel
    - c. Liletta® Levonorgestrel-Releasing Intrauterine System approved 2015, 3-year effectiveness, 18.6 mcg/day dose of levonorgestrel
    - d. Kyleena™ Levonorgestrel-Releasing Intrauterine System approved 2016, 5-year effectiveness, 17.5 mcg/day dose of levonorgestrel
  - 2. Copper-containing IUC (Cu-IUD)
    - a. Copper T- 380 Paragard® Intrauterine Device (TCu380A) approved 1988, 10-year effectiveness
- B. Effectiveness: All IUC methods are extremely effective in preventing pregnancy (>99%) once properly inserted.
  - 1. Levonorgestrel-releasing IUCs (LNG-IUD)
    - a. LNG-IUS typical use failure rate: 0.1%
    - b. Over 5 years the LNG-IUS typical use failure rate is 0.71%.
  - 2. Copper T- 380 Paragard® Intrauterine Device (Cu IUD).
    - a. Copper IUD typical use failure rate/year: 0.8%.
    - b. Over the 10 years of use the failure rate is 2%.
- C. Mechanism of action: The mechanisms of action for the methods are as follows:
  - 1. Levonorgestrel IUC
    - a. Thickened mucus impairs sperm penetration
    - b. Foreign body reaction is spermicidal
  - 2. Copper T – 380 IUD – approved for 10 years of use
    - a. Foreign body reaction is spermicidal
    - b. Copper impairs sperm motility and capacitation

#### D. IUC Choice/Comparison

Copper T 380A		LNG IUS			
Brand Name	<i>ParaGard</i>	<i>Mirena</i>	<i>Skyla</i>	<i>Liletta</i>	<i>Kyleena</i>
<b>Description</b>	T-shaped polyethylene frame with approximately 176 mg of copper wire coiled along the vertical stem and a 68.7-mg collar on each side of the horizontal arm	T-shaped polyethylene frame with a steroid reservoir containing 52 mg of LNG; releases approximately 20 mcg per day, decreasing to half that value after 5 years	T-shaped polyethylene frame with a steroid reservoir containing a total of 13.5 mg of LNG; releases approximately 14 mcg per day after 25 days, decreasing to 5 mcg per day after 3 years	T-shaped polyethylene frame with a drug reservoir containing 52 mg of LNG, packaged within a sterile inserter; releases approximately 18.6 mcg per day, decreasing to 12.6 mcg per day at 3 years	Works by releasing a low amount of the progestin, levonorgestrel (17.5 mcg a day); thickens cervical mucus and makes it harder for sperm to move.
<b>Duration of approved use</b>	10 years	5 years	3 years	3 years	5 years
<b>Efficacy</b>	> 99%	> 99%	> 99%	> 99%	>99%
<b>Size of device*</b>	32 mm horizontally and 36 mm vertically*	32 mm both horizontally and vertically	28 mm horizontally and 30 mm vertically	32 mm both horizontally and vertically	28 mm horizontally and 30 mm vertically.



					the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether.
<b>Special Benefits</b>	<p>Can be used as emergency contraception --prevents pregnancy when inserted up to 5 days after unprotected sex</p> <p>Contains no hormones--good contraceptive choice for women who cannot or prefer not to use estrogen</p> <p>Can use while breastfeeding</p> <p>No pill to take daily</p>	<p>Can use while breastfeeding</p> <p>No pill to take daily</p> <p>May reduce period cramps and make period lighter</p> <p>Good contraceptive choice for women who cannot or prefer not to use estrogen</p>	<p>Can use while breastfeeding</p> <p>No pill to take daily</p> <p>May reduce period cramps and make period lighter</p> <p>Good contraceptive choice for women who cannot or prefer not to use estrogen</p>	<p>Budget-friendly</p> <p>Can use while breastfeeding</p> <p>No pill to take daily</p> <p>May reduce period cramps and make period lighter</p> <p>Good contraceptive choice for women who cannot or prefer not to use estrogen</p>	<p>The smallest 5-year IUD</p> <p>Can be used whether or not have carried a baby</p> <p>Estrogen-free</p>

\*Smaller size may make IUDs easier and less painful to insert smaller size may also be better tolerated by women who have a smaller uterus—such as young teens and perimenopausal women and may be a little less likely to be expelled in women who have never had a baby or in younger women.

## II. PATIENT SELECTION

- A. Indications:
1. Contraceptive implants and intrauterine devices (IUD) are top-tier contraceptive options and should be highly encouraged for all women, *especially adolescents*.
  2. Implants and IUDs have lower failure (pregnancy) rates, higher continuation rates and improved safety when compared with other reversible hormonal or non-hormonal methods of contraception.
  3. If patients decline the contraceptive implant or IUDs, alternate, less-effective contraceptive methods should be initiated.
  4. All IUDs can also be safely used in patients who are breastfeeding.
  5. IUC use in nulliparous women: Research consistently shows that IUDs are effective and safe contraceptive devices for nulliparous women.
  6. The LNG-IUS (Mirena®) is also FDA-approved for the treatment of menorrhagia. This method can/should be offered as a therapeutic option for women with menorrhagia, regardless of if they require contraception (eg: after tubal sterilization)
- B. Contraindications (USMEC 3--Risks outweigh advantages for method use; USMEC 4- Unacceptable risk for method use).
1. Current pregnancy (USMEC 4)
  2. Postpartum puerperal sepsis (USMEC 4)
  3. Post-septic abortion (immediate) (USMEC 4)
  4. Ischemic heart disease (current and history of) (LNG continuation is USMEC 3)
  5. Systemic Lupus Erythematosus- Positive (or unknown) antiphospholipid antibodies (LNG USMEC 3)
  6. Systemic Lupus Erythematosus with severe thrombocytopenia (CU initiation USMEC 3)
  7. Gestational trophoblastic disease (persistently elevated  $\beta$ -hCG levels or malignant disease, with evidence or suspicion of intrauterine disease (initiation USMEC 4)
  8. Unexplained vaginal bleeding before evaluation (initiation USMEC 4)
  9. Breast cancer (current, LNG USMEC 4) (past and no evidence of current disease for 5 years, LNG USMEC 3)
  10. Distorted uterine cavity or other anatomical abnormalities (USMEC 4)
  11. Cervical cancer (initiation USMEC 4)
  12. Endometrial cancer (initiation USMEC 4)
  13. Pelvic inflammatory disease current (initiation USMEC 4)
  14. Current purulent cervicitis, chlamydial infection or gonorrhea (initiation USMEC 4)
  15. Cirrhosis (severe-decompensated) (LNG USMEC 3)
  16. Liver tumors (benign hepatocellular adenoma or malignant hepatoma) (LNG USMEC 3)
  17. Solid organ transplantation- complicated (initiation USMEC 3)
  18. Pelvic tuberculosis (initiation USMEC 4) (continuation USMEC 3)
  19. Known or suspected allergy to copper (Copper IUD only)
  20. History of Wilson's Disease (Copper IUD only)
  21. Small uterine cavity with sounding less than 6.0 cm

- C. The following factors should be considered in the risk/benefit evaluation and decisions regarding individualized management must be based on protocols approved by the site Medical Director or clinic physician. The patient must sign the consent form IUC for Women with Special Considerations if she has:
  - 1. Patient or her partner with multiple sexual partners (LNG-IUS only)
  - 2. Increased risk for STIs, (USMEC 2, 3)
  - 3. Previous IUC intolerance, expulsion or failure
  - 4. Suspected or known uterine perforation during uterine sounding with the current procedure.

### III. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.

### IV. MEDICAL SCREENING AND EVALUATION

- A. Targeted medical evaluation (history, physical examination and laboratory testing as indicated) should be completed prior to the provision of an IUC.
- B. The patient must complete a medical history which the clinician will review for determination of conditions which might affect the decision for IUC use (for example, possible pregnancy, risk for STIs).
- C. Gonorrhea/Chlamydia testing:
  - 1. Chlamydia/gonorrhea testing can be done in high-risk populations to assure negative results.
  - 2. In the absence of signs or symptoms of cervicitis, testing can be done at time of insertion.
    - a. If the patient has clinical signs for cervicitis, IUC insertion at that time is contraindicated until cervicitis is ruled out.
  - 3. If testing at time of insertion is positive, the patient should be treated, but the IUC does not need to be removed unless there are signs or symptoms of PID.
  - 4. IUD insertion should not be delayed for pap or STI screening (in patients without clinical concern for cervicitis)
- D. Prior to insertion, a pelvic exam including a speculum and bimanual exam must be done to determine uterine size, position and any degree of uterine flexion.
- E. Patients transferring from another provider must have a blood pressure measurement prior to providing IUC.

### V. TIMING OF INSERTION AND INSERTION PROCEDURE

- A. Only clinicians (physicians, NP, PAs, CNMs) with training and demonstrated skill in successful IUC insertion should insert IUCs. The site medical director should approve clinicians to be eligible to provide this service.
- B. For Insertion Procedure, follow manufacturer's instructions in package insert.
- C. A system & protocol must be in place for the management of vaso-vagal reactions.
- D. The table below should be followed when inserting an IUC. Alternative timings must be individualized to ensure adequate contraceptive protection and patient safety.

Current Method	IUC Insertion	Back- up
None	<ul style="list-style-type: none"> <li>■ First 7 days of normal menses</li> <li>■ Anytime during cycle if certain patient is not pregnant **</li> </ul>	<ul style="list-style-type: none"> <li>■ None</li> <li>■ For LNG IUD, Back up required if more than 7 days since onset of normal menses.</li> </ul>
All hormonal methods (when used reliably)	<ul style="list-style-type: none"> <li>■ For users of OCs, Ring, or Patch, may insert IUD at any time in cycle. Or patient may continue her method for rest of cycle.</li> </ul>	<ul style="list-style-type: none"> <li>■ For Copper T IUD users, hormonal method may be stopped immediately.</li> <li>■ For LNG users, continue method for seven days.</li> </ul>
Non-hormonal methods	<ul style="list-style-type: none"> <li>■ At any time in the cycle if pregnancy is reliably excluded.**</li> </ul>	<ul style="list-style-type: none"> <li>■ For copper T IUD users, No back-up needed</li> <li>■ For LNG IUD users, back up is required if it has been more than seven days since the onset of a normal menses.</li> </ul>
First-Trimester Spontaneous or Induced Abortion	<ul style="list-style-type: none"> <li>■ Immediately</li> <li>■ Or any time thereafter in appropriate candidates</li> </ul>	<ul style="list-style-type: none"> <li>■ None</li> <li>■ For LNG users, back up method for 7 days</li> </ul>
Second-Trimester Abortion	<ul style="list-style-type: none"> <li>■ Immediately, by an experienced, specially-trained clinician only. The patient must be informed of the increased risk of expulsion.</li> <li>■ Or wait at least four weeks</li> </ul>	<ul style="list-style-type: none"> <li>■ For copper IUD users, no back-up needed</li> <li>■ For LNG users, back up method for 7 days</li> </ul>

	(uterine involution)	
Post Delivery (breast feeding or non-breast feeding) (vaginal or caesarean delivery)	<ul style="list-style-type: none"> <li>■ <math>\geq 4</math> weeks for both, assure patient is not pregnant** (uterine involution)</li> </ul>	<ul style="list-style-type: none"> <li>■ For copper T users, no back-up needed</li> <li>■ For LNG users, back-up method for 7 days</li> </ul>
As form of Emergency Contraception (EC) Copper IUD only	<ul style="list-style-type: none"> <li>■ Within 5 days of first act of unprotected intercourse</li> </ul>	<ul style="list-style-type: none"> <li>■ Can be left in as long-term contraceptive.</li> </ul>

\*\*The clinician can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy, has a negative urine pregnancy test and meets any of the following criteria:

- A. Has not had intercourse since last normal menses
- B. Has been correctly and consistently using a reliable method of contraception
- C. Is within the first seven days after normal menses
- D. Is within four weeks postpartum for non-lactating women
- E. Is within the first seven days post-abortion or miscarriage
- F. Is fully or nearly fully breastfeeding, amenorrheic, and less than six months postpartum
- G. Has had two negative pregnancy tests two weeks apart, with abstinence or reliable contraception in the interim

## VI. PATIENT EDUCATION/ INFORMED CONSENT

- All patients being provided intrauterine contraception should receive the following:
- A. Information/counseling regarding all contraceptive options available
  - B. Information specific to IUC method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues. (Patient education form available as stand-alone document)
  - C. Information that IUC does not offer protection against STIs/HIV, that routine use of condoms should be encouraged to decrease STI risk
  - D. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same provided to the patient upon request
  - E. If IUC is being provided/prescribed to a patient with risk factors, then a *Request for Contraception for Women with Risk Factors* form should be reviewed and signed (available as a stand-alone document)
  - F. Patient should be provided with and given instruction/counseling on importance of reading the Patient Package Insert (PPI)



- G. Patient should be provided with user card that comes with the IUC kit (insertion date, lot #, removal date)
- H. Patient should be provided with post-insertion instructions
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

## VII. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

- A. Irregular Bleeding and Amenorrhea
  - 1. LNG-IUD: It is expected that users will have an increased number of days of spotting and bleeding, especially in the first 90-180 days of use. Approximately 20-40% of users will have amenorrhea after 12 months of use.
    - a. Education regarding the possibility of unscheduled bleeding and possible amenorrhea with IUD use should be conducted prior to method initiation
    - b. There is no strong evidence to support any particular treatment of unscheduled bleeding with IUD use. COCPs can be used for one to three months (as long as no contraindications exist to CHC) with the goal of decreasing intermenstrual bleeding once OCP use is stopped, but there is not good evidence to support this practice.
    - c. Amenorrhea does not need to be treated
  - 2. Copper T-380: Intra-menstrual bleeding may occur during the first 2-3 months of use. Menses may be heavier and longer.
    - a. Nonsteroidal antiinflammatory drugs (NSAIDs) for five to seven days can reduce abnormal menstrual bleeding and dysmenorrhea associated with the copper IUDs.
    - b. Rule out pregnancy if any delayed menstrual period.
  - 3. During use of any IUD, if the patient has persistent unexpected vaginal bleeding, unexpected delayed menstruation or pregnancy symptoms, a urine pregnancy test should be performed immediately.
- B. Patient unable to feel strings:
  - 1. Appointment ASAP. Advise patient to use back-up birth control method until she can be evaluated.
  - 2. If coitus within last 120 hours, emergency contraception should be recommended.
- C. Clinician unable to see strings upon exam: Attempt retrieval using cytobrush insertion into the endocervical canal. Rotate brush 180 degrees and remove brush gently. If strings retrieved, reassure patient. If strings not retrievable:
  - 1. Determine the IUC location. Advise patient to use back-up method until evaluation can be made whether IUC is in uterus, has been expelled or is in the abdominal cavity.
  - 2. Consult with medical director regarding referral for ultrasound. (If IUC cannot be located by ultrasound, may need to refer for abdominal x-ray).
  - 3. If IUC has not been expelled, consult with OB/GYN for management/removal
- D. Patient presents with:
  - 1. Trichomonas, Chlamydia, +/- Gonorrhea, PID.
    - a. Treat infection per current CDC STD Treatment Guidelines.
    - b. Discuss with patient risk factors for infection and sequelae

2. Vulvocandidiasis or Bacterial Vaginosis: treat per CDC guidelines; no need to remove IUC.
3. Actinomyces on pap smear – note a large majority of IUC users have asymptomatic colonization.
  - a. Patient must be examined for evaluation of pelvic infection.
  - b. If patient has symptoms for infection, consult an Ob/Gyn for immediate treatment.
  - c. If patient does not have symptoms of infection, the IUC is safe to leave in place. Patients should be counseled regarding this diagnosis, symptoms of infection, and may decide if they would like to continue use of the IUC or switch methods.
4. Pregnancy – failure rate of IUC is extremely low.
  - a. Perform highly sensitive pregnancy test. If positive, perform pelvic exam and order ultrasound to ensure pregnancy is not ectopic.
  - b. If ectopic suspected or confirmed, refer out for emergency care.
  - c. If pregnancy is in the uterus, the IUC should be removed in select circumstances (depending on the location of the pregnancy, the location of the IUD and visibility of the IUD strings). Removal of IUC reduces the risk of spontaneous abortion. If IUC cannot be removed (strings not visible), refer immediately to OB/ GYN.
  - d. Inform patient of risk of spontaneous abortion and sepsis and advise to report for emergency care if these develop prior to referral visit.

#### VIII. FOLLOW-UP

- A. Advise patient to report any of the following:
  1. Pregnancy symptoms
  2. If unable to feel string
  3. Suspected or confirmed IUC expulsion
  4. Bleeding that is extremely heavy or lasts longer than 2 weeks
  5. Continuous lower abdominal pain, or pelvic pain with a fever
  6. Any severe medical problem that develops such as DVT or pulmonary embolism, stroke, myocardial infarction, jaundice, hypertension (LNG-IUS only)
- B. Post insertion exams – patients should return for a post insertion check approximately 1-3 months (after first menses) to visualize strings, confirm placement and assess for signs of infection.
- C. Annual exams are to be scheduled by the patient.
- D. Removal-- When method change is desired, pregnancy is desired, or IUC has reached expiration date:
  1. Follow removal guidelines in the manufacturer's package insert
  2. Patients who have had intercourse without a barrier method should wait 5-7 days post coitus for removal.
  3. Counsel patients as indicated for alternate contraceptive methods or preconception health care information if pregnancy is desired. If patient desires another IUC, it may be inserted immediately after removal of the current IUC.

4. If there is difficulty with removal or IUC is embedded, consult with the site medical director or refer to an OB/GYN physician.

## IX. DOCUMENTATION

- A. Insertion Documentation:
  1. Order must be written in the medical record
  2. Documentation in the medical record for insertion must contain:
    - a. Position of uterus
    - b. Sounding measurement
    - c. Documentation of sterile technique
    - d. Information related to patient tolerance/problems
    - e. Lot number of IUC (must also be given to patient)
    - f. Patient checklists, consents
- B. Removal Documentation:
  1. Reason for removal
  2. Notations specific to removal
  3. Last coitus date
- C. All education/counseling must be documented.

## REFERENCES

1. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR / Vol. 65 / No. 3 / July 29, 2016
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